## SUMMARY OF EXPRESS TERMS

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions or modifications. The proposed regulatory amendments would permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These proposed amendments would also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The proposed regulatory amendments would also require hospitals to: develop disaster emergency response plans; maintain a 60-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 2800, and 2803 of the Public Health Law; and in the Commissioner of Health by Sections 576 and 4662 of the Public Health Law and Section 461 of the Social Services Law, Title 10 (Health) and Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Part 360 is added to Title 10, to read as follows:

Part 360 Surge and Flex Health Coordination System Activation During a State Disaster Emergency Declaration

Part 360. Surge and Flex System

Section 360.1. Administrative Purpose, Application and Scope

(a) Administrative purpose.

Hospitals across New York State, prior to the COVID-19 pandemic, rarely worked together or coordinated as a unified system. But a pandemic on the scale of the COVID-19 crisis demonstrated that hospitals could not meet the demand of the moment unless a new and innovative system was put into place requiring unprecedented coordination, cooperation, and agility. The New York State Department of Health takes note of the successful implementation of the Surge and Flex System by New York State's hospitals and offers these regulations as an additional way to strengthen the pandemic response. Surge and Flex Health Coordination System

Activation has helped hospitals respond to the COVID-19 state disaster emergency, and New York's hospitals have made commendable efforts to coordinate their response to the pandemic, to direct patients to the hospitals with the capacity to treat them, and to increase capacity as needed, during each wave of the pandemic.

The COVID-19 crisis demanded a new coordinated approach to ensure no one hospital was overwhelmed by COVID-19 patients or needed more ventilators, while a hospital nearby had capacity for more patients and excess equipment. It was imperative for government to coordinate and organize all hospitals under the umbrella of one unified system, and efficiently use all the resources available in the state to attempt to meet the significant demands of the crisis.

The "Surge and Flex" system is designed to create a single, coordinated statewide system to prevent a disaster from overwhelming any one hospital in the state. The purpose of this NYSDOH regulation is to institutionalize Surge and Flex operation, giving hospitals the time and guidance to adequately prepare for a potential future activation of Surge and Flex. This regulation provides the Department of Health with the necessary tools to enact Surge and Flex operation during another wave of COVID-19, or a future public health emergency. Further, this regulation is designed to help each hospital prepare for this contingency in order to ensure a straightforward transition from standard operating procedures to "Surge and Flex."

(b) Application and Scope. In the event of a State disaster emergency declared pursuant to section 28 of the Executive Law, the Commissioner may exercise the authorities granted in this Part, thereby maximizing the efficiency and effectiveness of the State's hospital systems and mitigating the threat to the health of the people of New York. Further, this Part establishes

certain ongoing emergency planning requirements, called the Surge and Flex Health Care Coordination System, for facilities and agencies regulated by the Department.

To the extent that any provision of this Part conflicts with any other regulation of the Department, this Part shall take precedence. All authorities granted to the Commissioner shall be subject to any conditions and limitations that the Commissioner may deem appropriate. The Commissioner may delegate activation of the authorities provided by this Part to appropriate executive staff within the Department. In the event that there are inconsistent statutes, which would preclude effectiveness of such regulation, such regulation shall be effective upon the suspension of such inconsistent statute by the Governor pursuant to authority in Article 2-B of the Executive Law, and such regulation shall immediately be effective.

Section 360.2. Surge and Flex Health Care Coordination System Requirements.

(a) In the event of a declared State disaster emergency, the Commissioner shall have all necessary authority and procedures to activate the Surge and Flex Health Care Coordination System (hereinafter "Surge and Flex System"), including the following:

(1) Increase Bed Capacity. At the Commissioner's direction, which shall be incremental and geographically targeted, health care facilities shall increase by up to 50% the number of acute care beds and/or change the service categories of beds certified or otherwise approved in any entity regulated by the Department. At the Commissioner's direction, health care facilities shall postpone up to 100% of non-essential elective procedures or allow such procedures only pursuant to such conditions as the Commissioner may determine. The Department shall establish procedures to approve temporary changes at regulated health care facilities to physical plants, to facilitate the increased capacity and shall expedite review of construction applications related to

temporary locations, provided that schematics are filed with the Department and patient safety is maintained.

(2) Enhanced Staffing Capacity. Health care facilities shall establish plans to meet enhanced staffing levels sufficient to ensure that the increased bed capacity has adequate staffing. The Commissioner may further expand or modify criteria for staffing. Health care facilities shall have access to a State-run portal for staffing needs identifying both volunteers and available staff; whether licensed or registered in New York State, or authorized or licensed to practice in any other state or Canada.

(3) Availability of Supplies and PPE. Health care facilities shall maintain and actively manage a supply of personal protective equipment (PPE) appropriate for use during a declared health emergency that could last at least 60-days pursuant to Section 405.11(g) of this Title. The Commissioner shall have all necessary authority to re-distribute the resources of a regulated entity if there is a determination that such resources are limited and in order to preserve the health and safety of New Yorkers, including:

(i) Requiring that any medical or other equipment that is held in inventory by any entity in the State, or otherwise located in the State, be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(ii) Requiring that the patient census be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(iii) For any infectious and communicable disease, ensuring that testing results are reported immediately if positive, and as determined by the Commissioner if such testing results are negative, via the electronic clinical laboratory reporting system or as the Commissioner may determine.

(iv) Suspending or restricting visitation, in accordance with the need to conserve PPE, and subject to such conditions or limitations as the Commissioner may determine.

(4) Statewide Coordination.

(i) Discharging, transfer, and receiving of patients. Health care facilities regulated by the Department shall, if directed to do so by the Commissioner, rapidly discharge, transfer, or receive patients, while protecting the health and safety of such patients and residents, and consistent with the Emergency Medical Treatment and Active Labor Act (EMTALA). The Department shall coordinate with health care facilities to balance individual facility patient load, and may promulgate further directives to specify the method and manner of transfer or discharge.

(ii) Designating Health Care Facilities as Trauma Centers. The Department is authorized to designate an entity as a trauma center; extend or modify the period for which an entity may be designated as a trauma center; or modify the review team for assessment of a trauma center; or change the level of acuity designation or health services of a facility or other determination about patient care as appropriate, including restricting admission or treatment to patients with a particular diagnosis.

(iii) Maintaining a Statewide Health Care Data Management System. Health care facilities or health systems shall report as directed by the Department any information necessary to implement the Surge and Flex System (e.g. available hospital beds, equipment available and in use) and the Department shall use that health facility or health system data in order to monitor, coordinate, and manage during the emergency.

Section 360.3. Hospital emergency Surge and Flex Response Plans.

(a) Every general hospital (hereinafter, "hospital") shall adopt a detailed emergency Surge and Flex Response Plan (hereinafter, "plan") that, at a minimum, includes the following elements:

(1) Bed surge plan. The plan shall explain how the hospital will increase the number of current staffed acute care operational beds to a number set by the Commissioner, which shall be up to a 50% increase of such beds within seven days from the date of the declaration of the state disaster emergency. For the purposes of this Part, an "acute care operational bed" means a bed that is staffed and equipped with appropriate infrastructure such that it can be used to deliver health care services to a patient. The Commissioner may further define the type of acute care operational beds for a given state disaster emergency, which may include isolation beds, intensive care (ICU) beds, pediatric and/or acute care beds. The plan shall contain scenarios for increases of current staffed acute care operational beds in phased increments, detailing the associated considerations for PPE, staffing, and other supplies and equipment, including whether the hospital can meet those requirements using internal resources and capabilities, as well as intra-system load balancing and postponement of some or all non-essential elective procedures. These plans shall inform the Commissioner's directives, which shall be incremental and geographically tailored at the Statewide, regional, or community level, as dictated by infection rate data.

(2) PPE surge plan. The plan shall explain how the hospital will increase its supply of personal protective equipment (PPE) appropriate for use in a pandemic to achieve continuous maintenance of its required 60-day supply of PPE, pursuant to section 405.11(g) of this Title. The plan shall list the contracted entities or other supply chain

agreements executed by the hospital. Such plan shall further include, as appropriate, how the hospital will repurpose existing equipment, replenish the inventory from other areas of the health system, and establish cooperative agreements to obtain PPE to accommodate supply chain interruptions. A PPE surge plan may provide for hospital utilization of some, but not all, of the stockpile reserves during a State disaster emergency, provided that within 30 days of the end of the State disaster emergency, the stockpile reserve is fully restored.

(3) Mass casualty plan. The plan shall explain how the hospital will receive and treat mass casualty victims, in the event of a secondary disaster arising from the interruption of normal services resulting from an epidemic, earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences, while addressing the continued need for surge capacity for the underlying state disaster emergency declaration.

(4) Staffing plan. The plan shall explain how the hospital will: identify and train backups for employees who may be unable to report to work during a pandemic; institute employee overtime protocols; and increase staffing by inter- and intra-system loan, cross-training, and volunteer programs, which would be operational on seven days' notice.

(5) Capital plan. The plan shall explain how the hospital shall ensure continuous operation of facilities and access to utilities, materials, electronic devices, machinery and equipment, vehicles, and communication systems. The plan shall ensure that the hospital routinely performs all required maintenance and peak load testing of its

infrastructure systems, including: electrical, heating, ventilation and air conditioning (HVAC), and oxygen supply.

(b) The Chief Executive Officer (CEO) of the hospital, or system if authorized by the Commissioner to report on a system-wide basis, shall certify to the review and approval of the plan, including an attestation that it can be implemented and achieved in the event of a declared disaster emergency. The CEO shall be responsible for ensuring that the plan is reviewed and updated, as necessary, periodically as specified by the Commissioner and shall re-certify that it is able to be implemented and achieved upon each review.

(c) The Department may require the hospital to submit its disaster emergency response plan and history of semi-annual certifications for review, and may require the hospital to make such amendments to the plan as the Commissioner deems appropriate, to ensure that the plan will achieve the requirements established in subdivision (a) of this section, including increases in bed capacity.

(d) In the event of a declared state disaster emergency, any or all hospitals shall execute their plans immediately upon the direction of the Commissioner.

(e) Additional preparedness requirements.

(1) PPE. Every hospital shall, at all times, continue to maintain the required 60-day supply of PPE appropriate for use in a disaster emergency including a pandemic, pursuant to section 405.11(g) of this Title.

(2) Information technology. Every hospital shall ensure that non-essential staff who are capable of working remotely in the event of an emergency are equipped and trained to do so, and that infrastructure is in place to allow for the repurposing of existing workspaces as needed when activating the Surge and Flex System.

(f) Reporting requirements during the activation of the Surge and Flex System.

(1) In the event of a declared state disaster emergency, upon the Commissioner's direction, hospitals or health systems shall report to the Department all data requested by the Commissioner, in a manner determined by the Commissioner under Section 306.2. Such data may include, but shall not be limited to:

(i) Bed availability, both in total and by designated service.

(ii) Bed capacity, meaning acute care operational beds as defined in paragraph (a)(1) of this Section.

(iii) Patient demographics.

(iv) Other health statistics, including deaths.

(v) PPE and other supplies, in stock and ordered.

(vi) PPE and other supply usage rates.

(2) Such reports shall be submitted periodically as determined by the Commissioner, except and unless otherwise directed by the Department.

Section 360.4 Clinical laboratory testing

(a) In the event of a declared state disaster emergency, the Commissioner shall have all necessary authority to:

(1) Authorize clinical laboratories to operate temporary collecting stations to collect specimens from individuals.

(b) In addition, and to the extent consistent with any Executive Order issued by the Governor, the Commissioner shall have all necessary authority to:

(1) Waive permit requirements for clinical laboratories and establish minimum qualifications to allow non-permitted clinical laboratories to accept and test specimens from New York State, provided that such laboratories must meet any federal requirements.

(2) Establish minimum qualifications of individuals that may perform clinical laboratory tests, provided that such persons meet federal requirements.

(3) Allow clinical laboratories to accept specimens without an order, subject to a plan approved by Commissioner to ensure the result of any tests are reported to the patient or the patient's personal representative and there will be appropriate follow up with the patient based on the results.

(4) Authorize licensed pharmacists to order clinical laboratory tests, consistent with federal law, including certificate of waiver requirements.

(5) Permit licensed pharmacists to be designated as qualified healthcare professionals for the purpose of directing a limited service laboratory, pursuant to Section 579 of the Public Health Law.

(6) Permit licensed pharmacists to order and administer clinical tests.

(c) Prioritization of clinical laboratory tests. In the event the declared state disaster emergency requires utilization of clinical laboratory testing at a rate that exceeds available capacity, no laboratory shall perform such test unless the test has been ordered consistent with the testing prioritization published by the Commissioner.

(d) Reporting of results of any communicable disease during a Surge and Flex period shall be made immediately via the Electronic Clinical Laboratory Reporting system, if positive, and on a schedule as determined by the Commissioner if negative.

Subdivision (g) of section 405.24 of 10 NYCRR is amended to read as follows:

Emergency and disaster preparedness. The hospital shall have a written plan, rehearsed and updated at least twice a year, with procedures to be followed for the proper care of patients and personnel, including but not limited to the reception and treatment of mass casualty victims, in the event of an internal or external emergency or disaster arising from the interruption of normal services resulting from earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences. Personnel responsible for the hospital's accommodation to extraordinary events shall be trained in all aspects of preparedness for any interruption of services and for any disaster. This shall be in addition to the Surge and Flex Plan that is required pursuant to Part 360 of the Title.

Section 400.1 of 10 NYCRR is amended to read as follows:

(a) This Subchapter shall be known and may be cited as "Medical Facilities--Minimum Standards," and shall apply to medical facilities defined as hospitals within article 28 of the Public Health Law. The standards within a particular article shall constitute the minimum standards for the identified medical facility in addition to those standards that may apply to such facilities as set forth in Articles 1 and 3 of this Subchapter as applicable.

(b) During the period of a state disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay

action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 700.5 of 10 NYCRR is added to read as follow:

700.5 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority

under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (8) is added to subdivision (e) of section 1001.6 of 10 NYCRR, to read as follows:

(8) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 1.2 of 10 NYCRR is added to read as follows.

1.2 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Title, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (4) subdivision (g) of section 487.3 of 18 NYCRR is added to read as follows:

(4) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the

Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (6) subdivision (f) of section 488.3 of 18 NYCRR is added to read as follows:

(6) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (5) subdivision (g) of section 490.3 of 18 NYCRR is added to read as follows:

(5) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

## REGULATORY IMPACT STATEMENT

**Statutory Authority:**

The authority for the promulgation of these regulations with respect to facilities subject to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2). PHL Article 28 (Hospitals), section 2800, specifies: "Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article." PHL section 2801 defines the term "hospital" as also including residential health care facilities (nursing homes) and diagnostic and treatment centers (D&TCs). PHL section 2803 (2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of such health care facilities.

PHL section 4662 authorizes the Commissioner to issue regulations governing assisted living residences. Social Services Law (SSL) section 461(1) authorizes the Commissioner to promulgate regulations establishing standards applicable to adult care facilities. PHL section 576 authorizes the Commissioner to regulate clinical laboratories.

PHL section 225 authorizes the Public Health and Health Planning Council (PHHPC) and the Commissioner to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Upon the future declaration of any disaster emergency, any further authorization by the Governor pursuant to article 2-B of the Executive Law, if it should suspend any statutes which otherwise conflict with these regulations, will establish the immediate effectiveness of these provisions.

**Legislative Objectives:**

The objectives of PHL Article 28 include protecting the health of New York State residents by ensuring that they have access to safe, high-quality health services in medical facilities, while also protecting the health and safety of healthcare workers. Similarly, PHL Articles 36 and 40 ensure that the Department has the tools needed to achieve these goals in the home care and hospice spaces, and PHL section 4662 and SSL section 461 likewise ensure that the Department has appropriate regulatory authority with respect to assisted living residences and adult care facilities. PHL section 576 ensures that the Commissioner has appropriate regulatory authority over clinical laboratories. Finally, PHL section 225 ensures that the State Sanitary Code includes appropriate regulations in the areas of communicable disease control and environmental health, among others.

By permitting the Commissioner to temporarily suspend or modify regulatory provisions in each these areas, where not required by state statute or federal law, or where authorized by a

gubernatorial Executive Order, these amendments provide crucial flexibility for this and future emergency response efforts.

**Needs and Benefits:**

During a state disaster emergency, Section 29-a of the Executive Law permits the Governor to, among other things, "temporarily suspend specific provisions of any statute, local law, ordinance, or orders, rules or regulations, or parts thereof, of any agency during a state disaster emergency, if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the disaster."

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions or modifications. The proposed regulatory amendments would permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These proposed amendments would also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The proposed regulatory amendments would also require hospitals to: develop disaster emergency response plans; maintain a 60-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

During a state disaster emergency with significant public health impact, and where compliance with certain regulations may prevent, hinder or delay action necessary to cope with the disaster, as is the case with COVID-19, this authority will ensure that the State has the most efficient regulatory tools to facilitate the State's and regulated parties' response efforts to Surge and Flex the healthcare system statewide. Additionally, this authority will also ensure that the Department has the flexibility to impose additional requirements, where necessary, to ensure effective response to a declared state disaster emergency. Accordingly, these tools will help ensure the health and safety of patients and residents in New York State.

**Costs:**

**Costs to Regulated Parties:**

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within, and as part of, a coordinated response to a specific situation.

To the extent that additional requirements are imposed on regulated parties by these proposed regulatory amendments, most requirements would be in effect only for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible.

**Costs to Local Governments:**

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within and as part of a coordinated response to a specific situation.

To the extent additional requirements are imposed on local governments that operate facilities regulated by the Department, most requirements would be in effect only for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible.

**Cost to State Government:**

The administration and oversight of these planning and response activities will be managed within the Department's existing resources.

**Paperwork:**

It is not anticipated that the proposed regulatory amendments will impose any significant paperwork requirements. Although these proposed amendments require additional reporting,

these reports can be submitted electronically using the current platforms that facilities are already using. Moreover, such reporting requirements would only be activated during a declared state disaster emergency, thereby limiting the burden.

**Local Government Mandates:**

Facilities operated by local governments will subject to the same requirements as any other regulated facility, as described above.

**Duplication:**

These proposed regulatory amendments do not duplicate state or federal rules.

**Alternatives:**

The alternative would be to not promulgate the regulation. However, this alternative was rejected, as the Department believes that these regulatory amendments are necessary to facilitate response to a state disaster emergency.

**Federal Standards:**

42 CFR 482.15 establishes emergency preparedness minimum standards in four core areas including emergency planning, development of applicable policies and procedures, communications plan, and training and testing. These proposed amendments would complement the federal regulation and further strengthen hospitals' emergency preparedness and response programs.

**Compliance Schedule:**

These regulatory amendments will become effective upon publication of a Notice of Adoption in the New York State Register.

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## REGULATORY FLEXIBILITY ANALYSIS

**Effect on Small Business and Local Government:**

The proposed regulatory amendments would primarily affect health care professionals, licensed health care facilities, permitted clinical laboratories, emergency medical service personnel, providers, and agencies, and pharmacies.

**Compliance Requirements:**

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, as well as hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, which would apply regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans.

**Professional Services:**

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.

**Compliance Costs:**

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within and as part of a coordinated response to a specific situation.

To the extent additional requirements are imposed on small businesses and local governments by these proposed regulatory amendments, most requirements would only be in effect for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible. Ongoing costs requiring hospitals to maintain a minimum PPE supply and ensure work from home capabilities should have been addressed throughout the ongoing COVID-19 pandemic, thereby limiting costs of continued implementation. Ongoing costs related to hospital development of disaster emergency response plan will complement and build upon existing planning documents that hospitals are already required to have, which also limits costs.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the proposed regulatory amendments.

**Minimizing Adverse Impact:**

Although the proposed regulatory amendments impose some additional requirements on regulated parties, most of these requirements are only triggered during a declared state disaster

emergency.  Proposed amendments that would impose ongoing requirements would only apply to hospitals, and as noted above, will largely be a continuation of the efforts already being employed by these entities.

**Small Business and Local Government Participation:**

Due to the emergency nature of COVID-19, small businesses and local governments were not consulted.

## RURAL AREA FLEXIBILITY ANALYSIS

**Type and Number of Rural Areas:**

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), "rural area" means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein." The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

| | | |
|---|---|---|
| Allegany County | Greene County | Schoharie County |
| Cattaraugus County | Hamilton County | Schuyler County |
| Cayuga County | Herkimer County | Seneca County |
| Chautauqua County | Jefferson County | St. Lawrence County |
| Chemung County | Lewis County | Steuben County |
| Chenango County | Livingston County | Sullivan County |
| Clinton County | Madison County | Tioga County |
| Columbia County | Montgomery County | Tompkins County |
| Cortland County | Ontario County | Ulster County |
| Delaware County | Orleans County | Warren County |
| Essex County | Oswego County | Washington County |
| Franklin County | Otsego County | Wayne County |
| Fulton County | Putnam County | Wyoming County |

| | | |
|---|---|---|
| Genesee County | Rensselaer County | Yates County |
| | Schenectady County | |

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

| | | |
|---|---|---|
| Albany County | Monroe County | Orange County |
| Broome County | Niagara County | Saratoga County |
| Dutchess County | Oneida County | Suffolk County |
| Erie County | Onondaga County | |

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans. This regulation provides that the Commissioner's directives shall be incremental and geographically tailored and targeted at the Statewide, regional, or community level, as dictated by infection rate data.

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.

**Compliance Costs:**

As a large part of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to public and private entities in rural areas.

To the extent additional requirements are imposed on public and private entities in rural areas by these proposed regulatory amendments, such requirements would only be in effect for the duration of a declared state disaster emergency.

Lastly, per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

Although the proposed regulatory amendments impose additional requirements on regulated parties, including those in rural areas, most of these requirements are only triggered during a declared state disaster emergency. Proposed amendments that would require disaster emergency preparedness planning on the part of regulated parties will complement and build upon existing state and federal planning requirements.

**Rural Area Participation:**

Due to the emergency nature of COVID-19, parties representing rural areas were not consulted in the initial draft. However, parties representing rural may submit comments during the notice and comment period for the proposed regulations.

## JOB IMPACT STATEMENT

The Department of Health has determined that these regulatory changes will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

## ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received comments regarding the proposed addition of Part 360 to Title 10 of the New York Codes, Rules and Regulations (NYCRR); the proposed addition of Sections 1.2, 700.5, and 1001.6(e)(8) to Title 10 of the NYCRR; the proposed amendments to Sections 400.1 and 405.24(g) of the NYCRR; and the proposed addition of Sections 487.3(g)(4), 488.3(f)(6), and 490.3(g)(5) to Title 18 of the NYCRR. The comments and the Department's responses thereto are summarized below.

**Comment:** A private individual commented that the proposed regulations are an unlawful overreach by a State agency, constitute government takeover of private facilities, and will lead to death and staffing shortages in regulated facilities.

**Response:** First, contrary to the commenter's assertion, the Commissioner of Health (Commissioner) has legal authority to promulgate this regulation. Such authority as it relates to facilities licensed pursuant to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2); PHL section 4662 authorizes the Commissioner to issue regulations governing assisted living residences; PHL section 576 authorizes the Commissioner to regulate clinical laboratories; PHL section 225 authorizes the Public Health and Health Planning Council (PHHPC) and the Commissioner to establish and amend the State Sanitary Code provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York; and finally Social Services Law section 461(1) authorizes the Commissioner to promulgate regulations establishing standards applicable to adult care facilities. Second, this rule is not an unlawful exercise of government control over covered

facilities; rather, the rule imposes conditions of PHL Article 28 licensure by the Department on regulated healthcare facilities. Third, this regulation is intended to provide crucial flexibility for emergency response efforts to avoid loss of life and ensure the proper utilization of healthcare facility staff, contrary to the assertion that this regulation will result in healthcare staffing shortages and death. As such, the Department has not made changes to the regulation due to these comments.

**A healthcare trade association representing hospitals and health systems in New York State (hereinafter, "the association") made the following comments:**

**Comment:** The association supported that the proposed regulation requires the Commissioner to employ an "incremental and geographically targeted" approach before directing facilities to increase their percentage of acute care beds, and the association agreed with the regulation's approach to managing elective procedures, as set forth in Section 360.2(a)(1).

**Response:** The Department appreciates this support.

**Comment:** The association asked the Department to "explore and invest in medium- and long-term strategies" to address staffing shortages in healthcare facilities and take staffing shortages into consideration when surge staffing is implemented pursuant to Section 360.2(a)(2) of the proposed regulation.

**Response:** The Department is committed to engaging with stakeholders on a regular basis to address the important issue of staffing shortages in healthcare facilities. However, such conversations are beyond the scope of this regulation and therefore no changes to the rule are necessary to address this comment.

**Comment:** Regarding the 60-day personal protective equipment (PPE) requirements set forth in Section 360.2(a)(3), the association requested that the Department improve its strategy when collecting information from regulated facilities about PPE stockpiles and requested that the Department share "consistent, standardized data definitions that factor in single-use and multi-use products and use agreed-upon burn rate methodologies."

**Response:** The Department has promulgated emergency regulations amending Sections 405.11 and 415.19 of Title 10 of the NYCRR, titled "Hospital and Nursing Home PPE Requirements," which set forth specific definitions and methodologies for calculating a hospital's required PPE stockpile; such regulations must be read in conjunction with these proposed regulations. When promulgating the "Hospital and Nursing Home PPE Requirements" regulation, the Department declined to calculate single- versus multi-use PPE differently because manufacturers have varying standards for reusability, there is no sound way for facilities to account for PPE that is being worn or washed when calculating the stockpile, and in the past facilities have inaccurately reported their reusable PPE amounts when the Department employed a standard adjustor to account for reusability. The Department is committed to regularly reviewing PPE reporting mechanisms, but such reporting strategies are outside the scope of this regulation. Accordingly, no modifications have been made to this regulation as a result of these comments.

**Comment:** The association asked the Department to identify and establish future efforts for Statewide coordination of discharge, transfer and receiving of patients to help hospitals load-balance patients.

**Response:** The Department is committed to engaging with stakeholders to identify discharge and transfer arrangements that will benefit facilities and enhance patient care while balancing patient populations during a surge. Moreover, the Department continues to operate a Surge Operation Center to facilitate patient load sharing and transfer patients when emergencies arise. Finally, the proposed rule does not preclude facilities from engaging with other facilities as well as the Department to coordinate patient load sharing (*see* 10 NYCRR 360.2[a][4]), and such efforts will be incorporated into the hospital's required Surge and Flex Response Plan. Given the ongoing coordination efforts permitted under the proposed regulation, the Department finds that no changes are necessary in response to this comment.

**Comment:** Regarding Section 360.2(a)(4)(ii), the association expressed confusion as to how this regulation would be integrated with the existing system of trauma designations and asked the Department to focus on preservation of trauma system resources.

**Response:** The proposed rule would allow the Department, when necessary to respond to a State of Emergency, to temporarily expand the number of facilities designated as trauma centers by authorizing the Department to designate an appropriate entity as a trauma center; extend or modify the period for which an entity may be designated as a trauma center; modify the review team for assessment of a trauma center; or change the level of acuity designation or health services of a facility when necessary. This rule is not intended to adversely impact currently-designated trauma centers, but rather expand the availability of trauma system resources when necessary for public health. Additionally, the Department is actively engaged with stakeholders to ensure appropriate designation of trauma centers outside of the surge and flex context. Accordingly, the Department finds that changes are unnecessary in response to this comment.

**Comment:** The association shared advice regarding data management based on the association's own experiences for purposes of implementing Section 360.2(a)(4)(iii) of the proposed rule.

**Response:** While the Department appreciates the recommendations shared by the association, because this comment does not recommend changes to the regulatory text the Department finds that no changes to the rule are required.

**Comment:** Regarding Section 360.3(a), the association asked the Department to clarify that its regulations align with the Emergency Preparedness Rule promulgated by the Centers for Medicaid & Medicare Services (CMS), which establish emergency preparedness minimum standards in four core areas.

**Response:** These proposed amendments will complement the federal regulation and further strengthen hospitals' emergency preparedness and response programs. Accordingly, no changes to this rule are necessary.

**Comment:** The association asked the Department to consider the burden of data gathering on end users, insofar as this regulation implements reporting requirements for covered entities (*see* Section 360.3[f]).

**Response:** The Department is sympathetic to the time staff must spend complying with facility reporting obligations. As such, the Department regularly reviews the data it requests to ensure need and relevance, streamline data collection, and reduce required data fields wherever possible to ensure healthcare facilities continue to primarily be engaged in patient care rather than data reporting. As such, the Department is committed to continuously engaging with the industry to

refine data collection wherever possible. However, as this comment does not concern requested changes to the proposed regulation, no changes will be made to in response to this comment.

**A healthcare trade association representing hospitals, health systems, nursing homes, and other healthcare providers in New York State (hereinafter, "the second association") submitted the following comments:**

**Comment:** The second association asked that the State extend the executive order related to healthcare workforce flexibilities to give healthcare facilities continued ability to address COVID-19 surges.

**Response:** The Governor of the State of New York, not the Commissioner, is authorized to issue executive orders during a declared State disaster emergency; as such, the Department finds that no changes are necessary to the regulation in response to this comment. However, the Department agrees to engage in ongoing efforts to make important investments in the healthcare workforce and welcomes continued conversations with stakeholders regarding ways to expand and help this crucial workforce.

**Comment:** The second association expressed concern that the reporting requirements are too onerous for healthcare facility staff.

**Response:** As stated above with respect to comments from the association, the Department is committed to continuously engaging with the industry to refine data collection wherever possible. No changes to the proposed regulation are necessary in response to this comment.

**Comment:** The second association recommended that the Department develop an early warning system to identify PPE supply chain issues to help facilities keep their stockpiles intact.

**Response:** The Department actively monitors PPE prices across several sales platforms to assess when supply chain issues may arise and will alert stakeholders, including healthcare trade associations, if such issues are detected. No changes to the proposed regulation are necessary in response to this comment.

**Comment:** The second association suggested that the Department consult with clinical experts to determine which forms of PPE are needed in facility stockpiles and asked that the PPE stockpile metrics account for reusable supplies.

**Response:** As indicated above in response to comments from the association, in promulgating the separate "Hospital and Nursing Home PPE Requirements" emergency regulation, the Department declined to calculate single- versus multi-use PPE differently because manufacturers have varying standards for reusability, there is no sound way for facilities to account for PPE that is being worn or washed when calculating a facility's stockpile, and facilities have inaccurately reported their reusable PPE stockpile in the past. With respect to the request that the Department consult with clinicians to determine which forms of PPE are necessary, the Department notes that clinical experts are retained on its staff and have been consulted when promulgating these regulations. Further, the Department based the required PPE on an expansive clinical study led by Johns Hopkins University as well as the forms of PPE recommended for use in healthcare facilities during the COVID-19 pandemic by CMS and the U.S. Centers for Disease Control and Prevention (CDC). Accordingly, the Department declines to make modifications to the regulation as a result of these comments.